UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC.,

Plaintiffs and Counterclaim Defendants

v.

HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.,

Defendants and Counterclaim-Plaintiffs.

Civil Action No. 3:11-cv-00760-JAP-TJB

Hon. Joel A. Pisano, USDJ
Hon. Tonianne J. Bongiovanni, USMJ

FINAL PRETRIAL ORDER

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16; and John E. Flaherty, Henry J. Renk, Bruce C. Haas and Joshua I. Rothman having appeared for the AstraZeneca Plaintiffs, and Mayra Tarantino, Mark Boland and Michael R. Dzwonczyk having appeared for the Hanmi Defendants; the following Final Pretrial Order is hereby entered:

1. JURISDICTION

This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, and 2202.

2. PENDING/CONTEMPLATED MOTIONS THE PARTIES AGREE THAT THE FOLLOWING MOTIONS ARE MOOT IF THE COURT PRECLUDES PLAINTIFF FROM ARGUING LITERAL INFRINGEMENT. (SEE TABS D&E FOR LEGAL ARGUMENT)

The following two formerly pending motions that were withdrawn will now be refiled in view of Defendants' reinsertion of issues relating to patent validity, namely anticipation and obviousness in view of the prior art Kohl reference,

1. Plaintiffs' Motion To Preclude Defendants From Relying On Evidence Of Experiments Performed By Mr. Brackeen For Which Samples And Documentation Have Not Been Produced.

2. Plaintiffs' Motion To Preclude Defendants' Expert Dr. Atwood From Relying On Evidence First Identified In His Reply Expert Report For Which Discovery Is Unavailable.

In view of Plaintiffs' assertion of a literal infringement case based on asking the Court to

reconsider its position for the third time regarding the controlling constructions of "alkaline salt" and "pharmaceutically acceptable salt" in the '504 and '192 patents (D.I. 257, reconsideration denied D.I. 232), Hanmi is asserting defenses based on the prior art Kohl reference, and the following withdrawn but fully briefed motions *in limine* are reinstated and will be refiled as directed by the Court:

1. Motion *in Limine* No. 1 -- Weissinger (D.I. 290-1).

2. Motion *in Limine* No. 5 -- Bartlett (D.I. 290-5).

3. STIPULATIONS FOR TRIAL

1. The asserted claims of the '504 patent are claims 1-6 and 10, but the parties will try only claims 2 and 4-6 as representative claims. If the Court finds that any one of these representative claims is infringed, then the parties agree that all asserted claims 1-6 and 10 are infringed (if not held invalid). If none of representative claims 2 and 4-6 is infringed, then the parties agree that the other asserted claims 1, 3 and 10 are not infringed.

2. The asserted claims of the '192 patent are claims 1, 2, 10-12 and 23, but the parties will try only claims 1 and 23 as representative claims. If the Court finds either claim 1 or claim 23 infringed, then the parties agree that all asserted claims 1, 2, 10-12 and 23 are infringed (if not held invalid). If neither representative claim 1 or 23 is infringed, then the parties agree that the other asserted claims 2 and 10-12 are not infringed.

3. If any one of '504 patent representative claims 2, 4 or 5 is found to be infringed, then the parties agree that, upon approval of Hanmi's NDA, commercialization of Hanmi's Proposed Products will constitute direct infringement of such claim(s), and inducement of infringement of '504 patent claim 6 based on the approved label.

4. If all representative '504 patent claims 2 and 4-6 are held invalid, then the parties agree that the other asserted claims 1, 3 and 10 also are invalid.

5. If both representative '192 patent claims 1 and 23 are held invalid, then the parties agree that the other asserted claims 2 and 10-12 also are invalid.

6. If the Court finds that neither of the representative claims of the '192 patent (1 and 23) are entitled to the benefit of the filing date of an earlier application that is prior to the date of publication of WO '988, or if the Court determines that WO 988 is admitted prior art, then the parties agree that those representative claims, and all other asserted claims of the '192 patent, are invalid as anticipated by WO '988.

7. The parties agree to divide the allocated trial time equally.

8. The parties agree not to seek any determination that this case is "exceptional" under 35 U.S.C. § 285.

See also **Exhibit A**.

4. PLAINTIFFS' CONTESTED FACTS.

N/A

5. DEFENDANTS' CONTESTED FACTS

N/A

6. PLAINTIFFS' WITNESSES

- Sverker von Unge, an AstraZeneca employee
- Magnus Larsson, Ph.D., a former AstraZeneca employee
- Tommy Andersson, Ph D., an AstraZeneca employee
- Bernhard Kohl, Ph.D. (by deposition)
- Jorg Senn-Bilfinger, Ph.D. (by deposition)

Summaries of the anticipated trial testimony of these witnesses are attached at **Exhibit B**.[1]

7. DEFENDANTS' WITNESSES[2]

Name	General Nature of Expected Testimony
Kweehyun Suh	Dr. Suh, Research Director at Hanmi Pharmaceutical Co., Ltd. ("Hanmi") Central Research Center, was involved in the development of the Hanmi product at issue in this action. He is expected to testify about the research and development leading to Hanmi's product, the obtaining of Hanmi patents on the product and process aspects, and relevant properties of the API, esomeprazole strontium tetrahydrate,

[1] In addition to Dr. Larsson's live testimony, AstraZeneca has indicated its intent to introduce the deposition testimony of Dr. Bernhard Kohl and Dr. Senn-Bilfinger, who are third parties. Hanmi objects to AstraZeneca's reliance on the testimony of Dr. Bernhard Kohl, Senn-Bilfinger and Magnus Larsson as not relevant to any issue properly in the case. In addition, it is Hanmi's position that Dr. Kohl's deposition testimony has already been recognized as inadmissible at trial given AstraZeneca's non-production of Dr. Kohl for deposition/cross-examination. (*See e.g.,* D.I. 256, Transcript of November 28, 2012 discovery conference, pp. 21:22-22:20; 24:3-26:3; D.I. 261, p. 3.) Hanmi reserves the right to raise these objections at trial. If Dr. Andersson is available for trial, Hanmi does not anticipate having to rely on deposition transcripts as per the section below regarding Hanmi fact witnesses.

[2] Although Defendants' descriptions of witness testimony are not as extensive as AstraZeneca's, Judge Bongiovanni indicated on May 13, 2013 that Hanmi's descriptions are in line with her directives to the parties on April 30, 2013.

	contained in Hanmi's product.
Jae-Hyun Park	Mr. Park is Director of Pharmaceutical Research Team at Hanmi's Pharmaceutical Research Center. He was on Hanmi's earlier witness list, but at present Hanmi does not anticipate calling him at trial provided Dr. Suh is able to be at trial.
(Kevin) KyuChan Kwon	Mr. Kwon, Director of Regulatory Affairs for Hanmi, is expected to testify about relevant aspects of Hanmi's 505(b)(2) NDA and Hanmi's product at issue which is the subject thereof, as well as relevant correspondence with the FDA.
Kyung Mi Park	Ms. Park is the Director of Clinical Research for Hanmi. She was on Hanmi's earlier witness list, but at present Hanmi does not anticipate calling her at trial provided Mr. Kwon is able to be at trial.
Sverker von Unge	Named inventor on the '504 patent. Hanmi intends to adduce live testimony from Mr. von Unge at trial on cross-examination regarding certain aspects of the patents-in-suit and Hanmi's defenses, and by agreement of the parties, and does not expect to use deposition excerpts, apart from impeachment purposes.
Tommy Andersson	AstraZeneca employee. Hanmi intends to introduce deposition testimony from Mr. Andersson at trial regarding certain aspects of the patents-in-suit and Hanmi's defenses.

8. EXPERT WITNESSES

A. Plaintiffs' expert witnesses are:

- Stephen G. Davies, D.Sc., University of Oxford, Chemical Research Laboratory, Mansfield Road, Oxford, OX1 3TA, United Kingdom
- René H. Levy, Ph.D., University of Washington, Department of Pharmaceutics, Box 357610, Health Sciences Center, H-Wing 272, Seattle, Washington 98195-7610
- Stephen R. Byrn, Ph.D., Purdue University, School of Pharmacy and Pharmaceutical Sciences, Department of Industrial and Physical Pharmacy, West Lafayette, Indiana 47906
- David A. Johnson, M.D., FACP, FACG, FASGE, Gastrointestinal and Liver Disease Specialists of Tidewater, PLLC/DBA Digestive & Liver Disease Specialists, 885 Kempsville Road, Suite 114, Norfolk, Virginia 23502
- Judi Weissinger, Ph D., Weissinger Solutions, Inc., 9360 W. Flamingo Blvd., Suite #110-553, Las Vegas, NV 89147-6446.[3]

[3] Hanmi reserves the right to object to Ms. Weissinger's testimony, for the reasons expressed in Hanmi's Motion *in Limine* No. 1.

- Paul A. Bartlett, Ph D., University of California Berkeley, Department of Chemistry, Berkley, California 94720-1460.[4]

Summaries of the anticipated trial testimony of these expert witnesses are attached at **Exhibit C**.

AstraZeneca does not question the qualifications of Hanmi's expert, Dr. Jerry Atwood, in the field of chemistry, but will demonstrate that Dr. Atwood is not qualified to offer opinions in the fields of pharmacology and clinical medicine.

B. Defendants' expert witnesses are:

Name	General Nature of Expected Testimony
Jerry L. Atwood Ph.D.	Dr. Atwood is a Professor of Chemistry at the University of Missouri. He is expected to testify on the issues as outlined in his expert reports. First, he will testify on the doctrine of equivalents, and specifically whether there are substantial differences between Hanmi's esomeprazole strontium tetrahydrate and the claimed esomeprazole salts in the '504 and '192 patents, which as construed by the Court do not literally include a strontium salt. Second, he will testify on various of Hanmi's invalidity defenses, including: lack enablement of asserted '504 and '192 patents based on salt scope; the '504 claims are invalid for double patenting based on AstraZeneca's prior '974 patent; and anticipation of the '192 claims based on WO '988.
Wayne J. Genck Ph.D.	Dr. Genck is a chemical engineering consultant with Genck International. He is expected to testify on the issues as outlined in his expert reports, including whether the claims of the patents-in-suit encompass hydrated forms of esomeprazole salts such as Hanmi's esomeprazole strontium tetrahydrate, and in the alternative, if the claims do cover such hydrated forms, whether they are invalid for lack of written description and/or lack of enablement. Dr. Genck will also testify about Hanmi's independent development of its accused product, including patents on its product and process aspects, as relevant to whether there are substantial differences vis-à-vis the patents-in-suit under the doctrine of equivalents. Dr. Genck is also expected to testify on indefiniteness of the '504 asserted claims.

In the event the Court permits AstraZeneca to re-litigate salt scope claim construction and assert literal infringement, Hanmi may call Mr. Marcus Brackeen of MonomerChem, Inc., Research Triangle Park, North Carolina, who is an organic chemist. Mr. Brackeen is expected to testify on the issues as outlined in his expert report, including the enabling disclosure of the Kohl DE '455 reference for the preparation of high optical purity enantiomers of esomeprazole and salts thereof.

[4] Hanmi reserves the right to object to the testimony of Dr. Bartlett to the extent indicated in in Motion *in Limine* No. 5.

9. PLAINTIFFS' EXHIBITS

A. Plaintiffs will submit its proposed trial exhibits and exhibit list on May 20, 2013 as called for on the Joint Trial Schedule. (D.I. 272).

B. Defendants will submit its objections to Plaintiffs' proposed trial exhibits on May 20, 2013.

10. DEFENDANTS' EXHIBITS

A. Defendants will submit its proposed trial exhibits and exhibit list on May 20, 2013 as called for on the Joint Trial Schedule. (D.I. 272).

B. Plaintiffs will submit its objections to Defendants' proposed trial exhibits on May 20, 2013.

11. PLAINTIFFS' LEGAL ISSUES

See **Exhibit D**.

12. DEFENDANTS' STATEMENT OF ISSUES AND DEFENSES See Exhibit E. Following AstraZeneca's statement on Sunday May 12, 2013 that it intends to seek to re-litigate certain claim constructions based on salt scope and assert literal infringement, the parties presented their views to Judge Pisano on the record Monday May 13, 2013. Subsequently, Ms. Bray advised counsel by email of Judge Bongiovanni's Order that Hanmi could present its objection in the Pretrial Order, along with an explanation of the issues that would be raised by permitting such re-litigation. Hanmi provides its views as requested, in Exhibit E. A ruling is respectfully requested before trial commences.

13. TRIAL COUNSEL (List the names of trial counsel for all parties).

AstraZeneca Plaintiffs

John E. Flaherty, Esq., McCarter & English

Henry J. Renk, Esq., Fitzpatrick, Cella, Harper & Scinto

Bruce C. Haas, Esq., Fitzpatrick, Cella, Harper & Scinto

Joshua I. Rothman, Esq., Fitzpatrick, Cella, Harper & Scinto

Einar Stole, Esq., Covington & Burling

Hanmi Defendants

Mayra V. Tarantino, Esq., Lite DePalma Greenberg, LLC

Mark Boland, Esq., Sughrue Mion, PLLC

Michael R. Dzwonczyk, Esq., Sughrue Mion, PLLC

John B. Scherling, Esq., Sughrue Mion, PLLC

Renita S. Rathinam, Esq., Sughrue Mion, PLLC

14. ESTIMATED LENGTH OF TRIAL

Trial is scheduled to start on May 21 and to continue through June 3.

AMENDMENTS TO THIS PRETRIAL ORDER WILL NOT BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT IS DISALLOWED.

Respectfully submitted.

Date: May 15, 2013

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Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

SO ORDERED:

Dated: May 15, 2013

Honorable Tonianne J. Bongiovanni
United States Magistrate Judge

A

I. The Parties

A. Plaintiffs

1. Plaintiff AstraZeneca AB ("AZAB") is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AZAB was a corporate name change from Astra Aktiebolaget.

2. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP ("AZLP") is a limited partnership organized under the laws of Delaware, with a principal place of business in Wilmington, Delaware.

4. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

5. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware.

B. Defendants

6. Defendant Hanmi USA, Inc. ("Hanmi USA") is a company organized and existing under the laws of New Jersey having a principal place of business in Florham Park, New Jersey.

7. Defendant Hanmi Pharmaceutical Co., Ltd. ("Hanmi Pharmaceutical") is a company organized and existing under the laws of South Korea having a principal place of business in Songpa-gu, Seoul 138-724 Korea.

8. Defendant Hanmi Fine Chemical Co., Ltd. ("Hanmi Fine Chemical") is a company organized and existing under the laws of South Korea having a place of business in Shiheung-City, Kyonggi-Do, Korea.

9. Defendant Hanmi Holdings Co., Ltd. ("Hanmi Holdings") is a company organized and existing under the laws of South Korea having a principal place of business in Paltan-myeon, Hwaseong-si 445-910, Korea.

II. Nature of the Action

10. This is an action for patent infringement under 35 U.S.C. § 271(e)(2)(A).

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1400(b), 2201 and 2202.

13. Hanmi USA has filed New Drug Application ("NDA") No. 202342 with the U. S. Food and Drug Administration ("FDA"), seeking approval to commercially sell an esomeprazole strontium product in 20 mg and 40 mg capsules ("Hanmi's Proposed Products").

14. Hanmi's NDA received tentative approval from the Food and Drug Administration on or about April 29, 2013.

15. Pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), in its NDA Hanmi USA certified to the FDA that U.S. Patent Nos. 5,714,504 ("the '504 patent") and 5,877,192 ("the '192 patent") are invalid or will not be infringed by the manufacture, use, or sale of Hanmi's Proposed Products ("Paragraph IV Certification").

16. Pursuant to 21 U.S.C. 355(b)(3), in a letter dated December 29, 2010 Hanmi USA notified Plaintiffs (collectively "AstraZeneca") that Defendants (collectively "Hanmi") had filed its NDA and that the NDA included a Paragraph IV Certification with respect to the '504 patent and the '192 patent.

17. On February 9, 2011, AstraZeneca filed a complaint against Hanmi,

alleging that Hamni's filing of its NDA No. 202342 infringed the '504 and '192 patents under 35 U.S.C. § 271(e)(2)(A).

18. Hanmi denies that its Proposed Products, or their use after approval, will infringe any asserted claim of the '504 or '192 patents, and alleges that the asserted claims are invalid.

19. Hanmi USA is the current holder of NDA No. 202342.

III. Omeprazole and Its Enantiomers

20. Omeprazole is the common name for the chemical compound whose formal chemical name is 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]- 1 H-benzimidazole.

21. The parties have sometimes referred to (–)-omeprazole-as esomeprazole.

22. AZLP is the holder of New Drug Application ("NDA") Nos. 21-153 and 21-154, by which the FDA granted approval for esomeprazole magnesium trihydrate products, 20 mg and 40 mg, which it sells under the name NEXIUM®.

IV. The Patents-In-Suit

A. The '504 Patent

23. The '504 patent issued to Astra Aktiebolaget based on a parent application (No. 08/376,512) filed in the United States Patent and Trademark Office ("USPTO") on January 23, 1995, naming as inventors Per Lennart Lindberg and Sverker Von Unge ("the parent application").

24. The parent application was a continuation-in-part ("CIP") of an earlier, grandparent application (No. 08/256,174) filed in the USPTO on May 27, 1994 ("the

grandparent application").

25. Original claim 1 of the '512 parent application, as filed on January 23, 1995, was as follows:

> 1. An optically pure enantiomeric compound comprising a Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.

26. In an Amendment filed February 12, 1997 in the '512 parent application, original claims 1-34 were cancelled, and claims 35-44 were added. Claims 35-44 eventually issued as claims 1-10 of the '504 patent.

27. The grandparent application claimed priority based on an application (No. 9301830) filed in the Swedish patent office on May 28, 1993 ("the Swedish priority application").

B. The '192 Patent

28. The '192 patent issued to Astra Aktiebolaget from an application (No. 08/833,962) filed in the USPTO on April 11, 1997, naming as inventors, Per Lindberg and Lars Weidolf ("the '192 patent application"). The '192 patent application was a CIP of the parent application.

VI. AstraZeneca's NEXIUM® Products

36. The active pharmaceutical ingredient in NEXIUM® is esomeprazole magnesium trihydrate.

37. NEXIUM® was first approved by the FDA in 2001.

38. NEXIUM® is approved for: treatment of gastroesophageal reflux disease

(GERD); risk reduction of NSAID-associated gastric ulcer; *Helicobacter pylori* ("*H. pylori*") eradication to reduce the risk of duodenal ulcer recurrence; and pathological hypersecretory conditions including Zollinger-Ellison syndrome.

VII. Hanmi's Proposed Products

39. The active pharmaceutical ingredient in Hanmi's Proposed Products is esomeprazole strontium tetrahydrate.

40. Each of Hanmi's Proposed Products contains one or more pharmaceutically acceptable carriers.

41. The esomeprazole strontium tetrahydrate in Hanmi's Proposed Products has an optical purity of at least 94% e.e.

42. The esomeprazole strontium tetrahydrate in Hanmi's Proposed Products has an optical purity of at least 98% e.e.

43. The esomeprazole strontium tetrahydrate in Hanmi's Proposed Products has an optical purity of at least 99.8% e.e.

44. The esomeprazole strontium tetrahydrate in Hanmi's Proposed Products is a solid, and not a liquid or a gas.

45. Gastroesophageal reflux disease (GERD), risk reduction of NSAID-associated gastric ulcer, *H. Pylori* eradication to reduce risk of duodenal ulcer recurrence, and pathological hypersecretory conditions, including Zollinger Ellison syndrome are conditions related to or caused by the production of gastric acid.

46. Upon approval, Hanmi's Proposed Products is intended to be prescribed for administration to human patients.

47. Man is a mammal.

48. Hanmi's Proposed Products are intended for prescription and administration for treatment the following conditions: gastroesophageal reflux disease (GERD); risk reduction of NSAID-associated gastric ulcer; *H. Pylori* eradication to reduce risk of duodenal ulcer recurrence; and pathological hypersecretory conditions, including Zollinger Ellison syndrome.

49. Hanmi's Proposed Products are intended for oral administration.

50. Each of Hanmi's Proposed Products is a capsule.

51. When approved, Hanmi's Proposed Product will not receive an "AB" rating from the FDA, and therefore will not be directly substitutable for Nexium® by a pharmacist without a specific prescription from a licensed healthcare professional.

VIII. Hanmi's Patents

52. Hanmi obtained U.S. Patent No. 7,576,219 B2 ("the '219 patent"), entitled Crystalline S-Omperazole Strontium Tetrahydate, Method For Preparing The Same, And Pharmaceutical Compositions Containing The Same, based on U.S. Application Serial No. 11/374,034 ("the '034 application") filed March 14, 2006, and issued August 18, 2009.

53. Hanmi asserts that the '219 patent claim encompasses Hanmi's Proposed Products.

54. Hanmi obtained U.S. Patent No. 8,106,076 ("the '076 patent"), entitled Crystalline S-Omeprazole Strontium Hydrate, Method For Preparing the Same, and Pharmaceutical Compositions Containing the Same, was filed April 17, 2009 as a continuation of the '034 application, and issued January 31, 2012.

55. Hanmi asserts that the '076 patent's claim 1 encompasses Hanmi's Proposed Products, which contain esomeprazole strontium tetrahydrate as the active pharmaceutical ingredient.

X. Facts Related to Hanmi's Invalidity Defenses

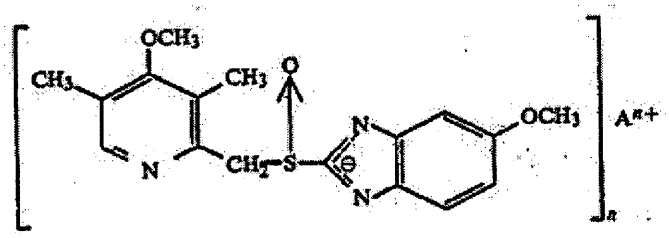
A. Double Patenting Based on AstraZeneca's '974 Patent

56. U.S. Patent No. 4,738,974 ("the '974 patent") issued on April 19, 1988.

57. The '974 patent is expired.

58. Claims 1, 5, 9 and 13 of the '974 patent are as follows:

1. A compound of the formula



wherein n is 1, 2, or 4; and A^{n+} is Li^+, Na^+, K^+, Mg^{2+}, or Ca^{2+}.

5. A pharmaceutical composition for inhibiting gastric acid secretion comprising a compound according to claim 1 in an amount effective to inhibit gastric acid secretion and a pharmaceutically acceptable carrier.

9. A method for inhibiting gastric acid secretion by administering to mammals an amount of a compound as defined in claim 1 sufficient to inhibit gastric acid secretion.

13. A method for the treatment of gastrointestinal inflammatory diseases in mammals by administering to mammals an amount of a compound as defined in claim 1 sufficient to treat gastrointestinal inflammatory disease.

'974 patent, cols. 9-10.

59. AstraZeneca obtained a Patent Term Extension pursuant to 35 U.S.C. § 156 for the '974 patent, based upon the regulatory review of the product Nexium® by the Food and Drug Administration (FDA) under new drug application (NDA) No. 21-153.

60. An April 19, 2001 Application for Extension of Patent Term under 35 U.S.C. § 156, the approved product, Nexium®, stated:

> Nexium™ Delayed-Release Capsules contain, as the active ingredient, esomeprazole magnesium, which is the magnesium salt of the S-isomer of omeprazole and the chemical name of which is bis (5-methoxy-2-[(S)-[(4-methoxy)-3,5-dimethyl-2-pyridinyl)methyl] sulfinyl]-1*H*-benzimidazole-1-yl) magnesium trihydrate.

61. AstraZeneca's Application for Extension of Patent Term indicated that claims 1-2, 4-6, 8-10, 12-14, 16-18 and 20 of the '974 patent read on the approved product, Nexium®.

62. AstraZeneca's Application for Extension of Patent Term at Exhibit C, page 1 stated that:

> Claim 1 encompasses lithium, sodium, potassium, magnesium and calcium salts of (5-methoxy-2-[[(4-methoxy)-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1*H*-benzimidazole), which is the chemical name for racemic omeprazole. Racemic omeprazole comprises a mixture of optical isomers of omeprazole, including the S-isomer. Nexium™ Delayed-Release Capsules contain esomeprazole magnesium. Esomeprazole magnesium is the magnesium salt of the S-isomer of omeprazole. Esomeprazole magnesium is therefore a compound within the scope of claim 1.

C. AstraZeneca's '070 and '085 Patents As Relating to "Hydrates" Defenses

63. AstraZeneca's U.S. Patent No. 7,411,070 ("the '070 patent") issued August 12, 2008, is entitled "Form of S-Omeprazole."

64. Claim 1 of the '070 patent reads: "1. The magnesium salt of S-omeprazole trihydrate."

65. AstraZeneca's U.S. Patent No. 6,369,085 ("the '085 patent") entitled "Form of S-Omeprazole."

66. Claim 1 of the '085 patent reads: "1. The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram . . . ."

67. The described process of Reference Example A in each of the '085 and '070 patents is identical to that of Example 6 in the '504 patent.

B

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF MR. SVERKER VON UNGE

Sverker von Unge is one of the inventors of the '504 patent. Mr. von Unge will testify that he was the first person to prepare the optically and chemically pure solid state alkaline salts of esomeprazole claimed in that patent. He will explain the research, experimentation, and other activities that ultimately led to this invention, as well as the unexpected and surprising beneficial properties of the compounds he synthesized.

Mr. von Unge obtained a licentiate of technology from Chalmers University in Gothenburg, Sweden in 1988. He will explain that while at Chalmers, he studied the stereochemistry of polymers. Part of his work involved creating and separating diastereomers of these compounds.

Mr. von Unge will testify that shortly after leaving University, he started working at Hässle, a predecessor to AstraZeneca. His first assignment was to synthesize new compounds for the omeprazole follow-up project. Mr. von Unge will explain that the goal of this project was to find a new compound similar to omeprazole, but with superior therapeutic properties. It was known that omeprazole was not effective at inhibiting gastric acid secretion in all patients. Thus, the follow-up project sought to find an omeprazole analog with decreased interindividual variability in gastric acid secretion inhibition, and reduced interaction with the metabolism of other drugs. Mr. von Unge and his colleagues synthesized hundreds of omeprazole analogs over the course of five to six years. However, although some compounds initially looked promising in preliminary tests, none was superior to omeprazole when considering all the relevant properties such as potency, bioavailability, and safety.

Mr. von Unge will explain that isolating the enantiomers of omeprazole or its analogs was not a part of the omeprazole follow-up project. The group made analogs of omeprazole and racemic mixtures and did not isolate the enantiomers of any of the analog compounds. Mr. von Unge will testify that AstraZeneca was not interested in separating the enantiomers of omeprazole because, among other reasons, the mechanism of action of omeprazole suggested the enantiomers would behave in the same way biologically. In fact, Mr. von Unge will explain that another group had performed *in vitro* studies demonstrating no difference between omeprazole and its partially separated enantiomers. This group also demonstrated that the isolated enantiomers would racemize, reverting to omeprazole over time. Consequently, there was little interest in the enantiomers of omeprazole at Hässle.

Mr. von Unge will testify that he became interested in separating diastereomers of omeprazole due to his work at University and his academic interest in stereoisomer separation techniques. He began working on this in his spare time, on the side of his regular work. Over the course of two years, he tried eight to ten different times to separate the diastereomers with no success. It was only in late 1991 that he finally succeeded.

Mr. von Unge will explain that once he had separated the diastereomers, he was able to isolate the enantiomers of omeprazole (esomeprazole and R-omeprazole). Esomeprazole was tested by analytical chemists and Mr. von Unge was surprised by the results. Esomeprazole had high optical purity and was surprisingly stable against racemization in alkaline (basic) conditions. Mr. von Unge will testify he was able to obtain the enantiomers in solid form by making their

alkaline salts. He was also able to increase the optical purity of the salts even further by crystallizing them. Other scientists at Hässle remained skeptical and did not want to invest time and resources into the enantiomers. Instead, they continued to focus on the omeprazole follow-up project, which was still making analogs of omeprazole.

As Mr. von Unge will testify, the enantiomers were evaluated in biological studies. In tests conducted on rats, R-omeprazole was unexpectedly more effective than esomeprazole or the racemate. Mr. von Unge and others at Hässle had previously believed that there would be no difference in the biological effects of the enantiomers. Interest in the enantiomers gradually started to increase, with the enantiomers of omeprazole finally becoming candidate drugs in late 1993. Mr. von Unge will explain that he was surprised again when the enantiomers were finally tested in human liver microsomes. In a human model, the efficacy was reversed and it was esomeprazole that was superior. It was an alkaline salt of esomeprazole (esomeprazole magnesium trihydrate) that would go on to be developed as the API in AstraZeneca's Nexium® product.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. MAGNUS LARSSON

Dr. Magnus Larsson is a former employee of AstraZeneca AB ("AZAB") where he held the following positions: (a) Process Chemist (March 1993 to end of 1993); (b) Project Leader/Process Chemist (end of 1993 to September 1995); (c) Team Manager (Section Manager) (October 1995 to August 2000); and (d) Head of Process Engineering (September 2000 to August 2002). In 1993, Dr. Larsson was asked to help develop or modify a manufacturing process to deliver sufficient quantities of single omeprazole enantiomers for human and toxicological testing.

Dr. Larsson obtained his M.S. in chemical engineering and his Ph.D. in organic chemistry from the Royal Institute of Technology in Stockholm, Sweden. After receiving his Ph.D., Dr. Larsson joined AZAB as a process chemist. He has authored publications addressing manufacturing processes related to pharmaceutical active ingredients, including the proton pump inhibitors omeprazole and esomeprazole.

In rebuttal to Hanmi's anticipation, obviousness and double patenting defenses, Dr. Larsson will testify that in 1993 he first attempted to synthesize single omeprazole enantiomers using an early process developed by Sverker von Unge at AZAB. He will explain that this process was extremely laborious and time intensive and unsuitable for large scale synthesis of single omeprazole enantiomers. Dr. Larsson will also testify that later in 1993 he became aware of a process disclosed in abandoned German application DE 403455 ("DE 455"); he was asked to determine whether that process could be used or modified to make the needed quantities of single omeprazole enantiomers. After repeated attempts, Dr. Larsson was unable to use or modify the DE 455 process to make stereochemically or chemically pure (+) or (–)-omeprazole enantiomers.

SUMMARY OF TESTIMONY OF TOMMY ANDERSSON, Ph.D.

Dr. Andersson joined Hässle AB (now AstraZeneca AB ("AZAB")), in 1978. In 1981, he moved to the clinical pharmacology group where he first became involved with omeprazole. In this capacity Dr. Andersson planned, monitored and evaluated Phase I studies, i.e. early-stage studies in humans to determine the pharmacology in general and pharmacokinetics in particular, of omeprazole. In 1993, after receiving his Ph.D in clinical pharmacology from the University of Gotenburg, Sweden, Dr. Andersson was appointed Project Team Leader for the Omeprazole Successor Project (the "Project"), which was an AZAB research program started in 1987 to find compounds therapeutically superior to omeprazole. Dr. Andersson was responsible for the testing of candidate drugs and evaluation of their properties as compared to omeprazole. Dr. Andersson held this position through 1996.

Dr. Andersson's testimony will be offered to demonstrate that in 1993 AZAB was not interested in the enantiomers of omeprazole believing that the enantiomers would not offer any improved properties over racemic omeprazole. Additionally, stability (enantiomers of esomeprazole were thought to be prone to racemization) and purification (optically pure enantiomers of omeprazole were not obtainable at this time) challenges discouraged any potential interest in esomeprazole. Instead, researchers at AZAB focused on molecules that were structurally similar to omeprazole.

Dr. Andersson will testify that the Project started as an effort to find compounds therapeutically superior to omeprazole. For example, it was well known that a subset of the population (poor metabolizers ("PMs")) cleared omeprazole through the liver slower than the general population (extensive metabolizers ("EMs")) leading to ten-fold higher blood concentration levels (as measured in AUC) in PMs versus EMs. Therefore, there was an interest in reducing variation between these population groups.

Dr. Andersson will testify that despite on-going skepticism, initial testing of esomeprazole in 1993 indicated to that it was stable against racemization, *in vivo*, and furthermore, that the enantiomers of omeprazole were cleared by the liver at a different rate than omeprazole and from each other in certain patient populations. This lead to the surprising discovery that the use of esomeprazole reduces interindividual variation from a ten-fold to a three-fold difference between PMs and EMs as compared to omeprazole. It was further surprising that this feature was unique to the enantiomers of omeprazole.

Dr. Andersson will testify that human clinical trials supported the discovery that esomeprazole increased AUC in EMs and decreased interindividual variation in between PMs and EMs.

Dr. Andersson will also testify that his declaration filed in the United States Patent and Trademark Office on February 12, 1997 in the prosecution of U.S. Patent No. 5,714,504 ("Andersson Declaration") summarizes the advantages described above and that the '504 patent issued after the examiner considered the Andersson Declaration.

SUMMARY OF DEPOSITION TESTIMONY OF DR. BERNHARD KOHL

In the 1980s and 1990s, Dr. Bernhard Kohl worked for Byk Gulden in Germany as a process chemist in Byk Gulden's proton pump inhibitor project; he was responsible for developing efficient and scalable methods for producing drug candidates. He was a co-inventor, along with Dr. Jorg Senn-Bilfinger, of the process described in Byk Gulden's German patent application DE 40 35 455 ("DE455"). In a deposition taken in an earlier AstraZeneca action (admissible in this action by stipulation), Dr. Kohl testified that the process described in DE455 is not suitable for preparing individual enantiomers of omeprazole in high chemical and optical purity or in solid state or highly crystalline form.

Dr. Kohl obtained his B.A. in 1976 and his Ph.D. in 1979 in Chemistry from the University of Munich. Upon graduation, he joined Byk Gulden in Konstanz, Germany, as a process chemist. He began working on Byk Gulden's proton pump inhibitor project in 1981, and worked on the process for preparing between 50 and 100 proton pump inhibitors, including pantoprazole, which is the active ingredient in Protonix®, a commercial proton pump inhibitor.

In 1990, Dr. Kohl was tasked with preparing individual enantiomers of pantoprazole for studies in rats. The process he developed for making individual pantoprazole enantiomers is described in DE455. Dr. Kohl explained that, as applied to pantoprazole, his process includes reacting racemic pantoprazole with another chiral compound, attempting the isolation of just one of the reaction products using a series of purification steps, and then removing the chiral compound appended to the isolated material to provide pantoprazole in enantiomerically enriched form. Dr. Kohl explained that his process afforded individual enantiomers of pantoprazole in at most 91% enantiomeric excess in crude form, but that the pantoprazole product was amenable to further purification by crystallization.

Dr. Kohl also testified that, when he applied the DE455 process to the preparation of the (+)-enantiomer of omeprazole, it did not work in the same manner as it had for pantoprazole. In the step requiring removal of the appended chiral compound, (+)-omeprazole decomposed, providing impure crude product in low optical purity and very low yield (1-4%) or none at all. And, unlike the individual enantiomers of pantoprazole, in the DE455 process (+)-omeprazole was not amenable to further purification by crystallization. Dr. Kohl also explained that aspects of his process make it unsuitable to the preparation of proton pump inhibitors on larger scales than those reported in DE455 (only 0.15 gram of crude (+)-omeprazole was obtained).

Dr. Kohl also testified that, because of the mechanism of action of this class of molecules—in which the chiral center is lost prior to reaction with and inhibition of the proton pump—Byk Gulden had no expectation of obtaining any therapeutic benefit with the individual enantiomers of pantoprazole or any other proton pump inhibitor.

SUMMARY OF DEPOSITION TESTIMONY OF DR. JORG SENN-BILFINGER

In the 1980s and 1990s, Dr. Jorg Senn-Bilfinger worked for Byk Gulden in Germany as a medicinal chemist, focused on gastrointestinal projects, including proton pump inhibitors. Along with Dr. Kohl, he was a co-inventor of the process described in DE455. Dr. Senn-Bilfinger testified that Byk Gulden was unable to obtain individual enantiomers of omeprazole in high chemical and optical purity using the DE455 process, and that Byk Gulden focused its drug discovery resources on the preparation of novel proton pump inhibitors rather than individual enantiomers of any such compound.

Dr. Senn-Bilfinger first became involved in chemistry with an apprenticeship at Dr. Karl Thomae (now Boehringer Ingelheim) in 1962. He subsequently earned his B.A. in 1975 and Ph.D. in 1978 in Chemistry at the University of Stuttgart, Germany. Upon graduation, he joined Byk Gulden as a medicinal chemist and worked on a variety of projects pertaining to gastrointestinal disorders. He began working on Byk Gulden's proton pump inhibitor project in 1981, and was involved in the design, synthesis, characterization or testing of more than 100 proton pump inhibitors, including pantoprazole. He also conducted research that led to the elucidation of the mechanism of action of proton pump inhibitors.

Dr. Senn-Bilfinger testified that, along with Dr. Kohl, he developed the DE455 process for preparing individual enantiomers of pantoprazole. Like Dr. Kohl, he testified about certain aspects and limitations of the process, and explained that, because Byk Gulden had no expectation of obtaining any therapeutic benefit with the individual enantiomers of any proton pump inhibitor, Byk Gulden allowed the DE455 patent application to go abandoned.

C.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. STEPHEN G. DAVIES

Dr. Stephen G. Davies is Professor of Chemistry at Oxford University. One area of focus in Dr. Davies research, and concerning which he has extensively consulted with pharmaceutical companies and founded his own company, is methods for preparing chiral compounds as individual enantiomers. Dr. Davies will testify concerning infringement and in rebuttal to many of Hanmi's invalidity defenses.

Dr. Davies obtained a B.A. in 1973 and a D.Phil. in 1975 in Chemistry from Oxford, and a D.Sc. degree in Chemistry from the University of Paris in 1980. Dr. Davies began teaching at Oxford in 1980 and was Chairman of the Department of Chemistry from 2006 to 2011. His teaching responsibilities include organic and pharmaceutical chemistry. He also leads a research group involved with the development of new synthetic methods, investigations into the mechanisms of chemical reactions, the total synthesis of complex molecules, and medicinal chemistry. Over the course of his career he has lectured extensively, published over 500 articles, obtained several patents, and received numerous awards in these areas.

Dr. Davies will testify that Hanmi's esomeprazole strontium API contains esomeprazole in the very high optical purity of the asserted claims, and that it exhibits sufficient crystallinity such that upon crystallization, the optical purity increases ('504 patent claim term "substantially crystalline form"). Dr. Davies will explain that esomeprazole strontium is an alkaline salt of esomeprazole, as that term would ordinarily be understood, meaning that like the claimed salts of esomeprazole, it is formed under basic conditions and consists of anionic (negatively charged) esomeprazole with a cationic (positively charged) counterion (strontium) rendering the overall salt uncharged. Dr. Davies will explain that this alkaline esomeprazole strontium salt, like the claimed alkaline esomeprazole salts and unlike the prior art forms of individual enantiomers of omeprazole, exists as a stable highly crystalline product that as a result is accessible in high optical purity, making it possible to take advantage of the beneficial properties of esomeprazole in therapy.

In rebuttal to Hanmi's noninfringement case, Dr. Davies will explain that any unclaimed different properties between the claimed salts, and between any of the claimed salts and Hanmi's strontium salt, have no bearing on the advantages of the claimed inventions over the prior art or the ability to utilize the esomeprazole salts in the manner claimed. Dr. Davies will also testify that nothing in the patent specifications or file histories indicate that AstraZeneca relinquished the scope of possible equivalents to the claimed salt forms, and indeed the prosecution history reflects an effort to broadly claim any pharmaceutically acceptable alkaline salt of esomeprazole. Finally, he will also explain that although a pharmaceutically acceptable strontium salt form of esomeprazole would not have been foreseeable when the patents-in-suit were filed and prosecuted, today the interchangeability is unquestionable.

In rebuttal to Hanmi's anticipation, obviousness and double patenting defenses, Dr. Davies will explain that the claimed inventions, particularly pure solid state forms of esomeprazole in high chemical and optical purity amenable to optical enrichment by crystallization, would not have been enabled by the prior art. In doing so, Dr. Davies will testify that the unsuccessful attempts by Byk Gulden's Drs. Kohl and Senn-Bilfinger and AstraZeneca's Dr. Larsson to apply the

DE455 method to obtain individual enantiomers of omeprazole are representative of the challenge preparing the claimed inventions actually presented.

In further rebuttal to Hanmi's anticipation, obviousness and double patenting defense, Dr. Davies will explain that the references relied upon by Hanmi fail to describe the claimed inventions, and that there would have been no motivation to attempt to prepare individual enantiomers of omeprazole due to the challenge, cost, and lack of expectation of meaningful therapeutic benefit. And Dr. Davies will testify that the beneficial chemical and optical stability and therapeutic advantages of esomeprazole and its alkaline salts over omeprazole would have been unexpected.

Finally, Dr. Davies will respond to Hanmi's numerous assertions that certain claim limitations were not reasonably conveyed or enabled as of the filing date of the applications leading to the patents-in-suit or predecessors, or that certain claim terms are indefinite.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. RENÉ LEVY

René H. Levy, Ph.D. is a Professor Emeritus in the Department of Pharmaceutics at the University of Washington. He had been a member of the faculty at the University of Washington for four decades, teaching, conducting extensive research, and publishing in the area of pharmaceutical sciences, including pharmacology, pharmacokinetics, and drug metabolism. In particular, his research has focused on pharmacokinetic studies involving absorption, distribution, metabolism, and excretion in humans and animal models; elucidating the metabolic pathways of drugs by metabolizing enzymes; and identifying mechanisms of metabolism-based drug-drug interactions.

Dr. Levy received his undergraduate degree in Pharmacy from the University of Paris, France and his Ph.D. in Pharmaceutical Chemistry from the University of California, San Francisco. Dr. Levy's additional qualifications and a list of his publications are identified in his curriculum vitae. As an expert in pharmacology, Dr. Levy will testify concerning infringement and in rebuttal to several of Hanmi's invalidity defenses.

Dr. Levy will testify that Hanmi's esomeprazole strontium and the claimed alkaline salts of esomeprazole are insubstantially different; their behavior in the body is exactly the same. Dr. Levy will explain how both compounds afford the same neutral esomeprazole upon administration, which after chemical conversion to a reactive species, binds to and thereby inhibits the proton pump responsible for gastric acid secretion. He will further explain that the administration of either esomeprazole strontium or the claimed alkaline salts elicits the same improved pharmacokinetic and pharmacodynamic properties.

Dr. Levy will also testify that the biological properties of the '192 patent claims are definite, and that such properties and neutral esomeprazole are enabled and adequately disclosed in the parent application, grandparent application, and Swedish priority application. He will further opine that neither Erlandsson (1990) nor DE '455 would have provided a person of ordinary skill in the art a motivation to develop an enantiomer of omeprazole (or its salts), and that such a person would have had no reasonable expectation of the improved properties of esomeprazole.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. STEPHEN R. BYRN

Stephen R. Byrn, Ph.D. received a B.A. in chemistry from DePauw University in 1966 and a Ph.D. in organic and physical chemistry from the University of Illinois in 1970. He is currently the Charles B. Jordan Professor of Medicinal Chemistry in the School of Pharmacy and Pharmaceutical Sciences and the Head of the Department of Industrial and Physical Pharmacy at Purdue University. He has been a member of the Purdue faculty since 1972 and regularly teaches courses on pharmaceutical solids, drug development, and other related topics.

Dr. Byrn's research focuses on the solid state chemistry of pharmaceutically important compounds and the processing and manufacturing of pharmaceuticals. He has authored over 150 articles in peer-reviewed academic journals and several book chapters concerning these and related topics. Dr. Byrn is also the founder of SSCI Inc. (now Aptuit Inc.), an analytical research laboratory specializing in the crystallization, stability, and polymorphism of pharmaceutical compounds. Dr. Byrn's additional qualifications and a list of his publications can be found in his curriculum vitae.

Dr. Byrn will provide background information concerning scientific principles and concepts related to solid state chemistry and the formulation of pharmaceuticals and opinions concerning both infringement and validity of the '504 and '192 patents.

Dr. Byrn will explain that Hanmi's proposed products contain a "solid state" salt of esomeprazole as required by the asserted claims of the '504 patent. He will explain that Hanmi's NDA establishes that its API is a crystalline powder, a form a person of ordinary skill in the art (POSA) would readily recognize as solid material.

Dr. Byrn will rebut Hanmi's contention that hydrated forms, such as Hanmi's esomeprazole strontium tetrahydrate, are excluded from the scope of the asserted claims of the '504 and '192 patents. He will explain that a hydrate of an esomeprazole salt is a solid form of that salt. Consistent with the court's construction of "solid state," a POSA would understand the '504 patent claims to cover pure alkaline salts of esomeprazole in any solid state form, including hydrates. He will also explain that a hydrated form of an alkaline salt of esomeprazole is an "alkaline salt" or "pharmaceutically acceptable salt" of esomeprazole. Hydrated and anhydrous forms contain the same cation (*e.g.*, magnesium) and the same anion (esomeprazole) and are thus the same salt.

Dr. Byrn will further testify that Hanmi's esomeprazole strontium tetrahydrate API is not substantially different from the esomeprazole salts claimed in the '504 and '192 patents. He will explain that Hanmi's API affords the same benefits over the prior art as the claimed salts. Like the claimed salts and unlike the prior art, Hanmi's API can be obtained as crystalline solid rather than an oil or syrup and is sufficiently pure to use as a pharmaceutical.

With respect to validity, Dr. Byrn will rebut Hanmi's contention that the '504 and '192 patent are invalid for lack of written description and enablement of hydrated forms of the alkaline salts of esomeprazole. Dr. Byrn will explain that the question of whether hydrates are disclosed and enabled is irrelevant because the claimed invention is directed to alkaline salts of esomeprazole

in ***any*** solid state form. Several advantages and benefits of the invention do not derive from the use of any particular solid state form, but instead from the use of solid state forms as opposed to syrups. He will explain that the patents describe and enable a POSA to make alkaline salts of esomeprazole as solid material. A POSA would not expect all solid forms of the claimed salts to be disclosed because it is simply not possible for a chemist to ever know with any degree of certainty whether all solid state forms of a compound have been identified.

In any event, Dr. Byrn will testify that hydrates are disclosed and enabled by the '504 and '192 patents. He will explain that metal salts and magnesium salts in particular are prone to form hydrates. As a result, because the '504 patent contains numerous examples where copious amounts of water are used, a POSA would expect the '504 patent procedures to produce hydrates. He will also explain that the examples of the '504 patent must have produced hydrated forms because no anhydrous forms of esomeprazole magnesium have been identified. Dr. Byrn will also discuss other strong evidence that the '504 patent examples produce hydrates including the inventor's notebooks and testimony, X-ray powder diffraction patterns, AstraZenca's representations to the patent office in later prosecution, and Hanmi's own admissions.

Dr. Byrn will also testify that the term "pure" in the '504 patent is not indefinite. The Court has construed this term to mean sufficiently free from chemical impurities to permit use in a pharmaceutical formulation. Dr. Byrn will explain that with the aid of FDA guidances, it is well within the ability of a POSA to determine the upper limit for any particular impurity that is permissible for use in a pharmaceutical formulation.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. DAVID A. JOHNSON

Dr. David A. Johnson is a Professor of Medicine and the Chief of Gastroenterology at the Eastern Virginia School of Medicine and works full-time in clinical practice with daily patient-care responsibilities. Dr. Johnson is board certified in gastroenterology and internal medicine and has been active in the field of gastroenterology for over twenty-eight years. As an expert in gastroenterology with extensive clinical experience, Dr. Johnson will testify as to infringement of Hanmi's Proposed Products and their contemplated use and in rebuttal to Hanmi's lack of written description, lack of enablement, obviousness and obviousness-type double patenting invalidity defenses.

Dr. Johnson obtained a B.A. in Psychology from the University of Virginia in 1976 and an M.D. from the Medical College of Virginia is 1980. Dr. Johnson was an intern at the Naval Hospital in Portsmouth, Virginia from 1980-1981 and a Medical Officer on the USS Sylvania from 1981-1982. Dr. Johnson did his residency in Internal Medicine at the Naval Regional Medical Center in Portsmouth, Virginia from 1982-1984 and a fellowship in Gastroenterology at the National Naval Medical Center in Bethesda, Maryland from 1984-1986.

Dr. Johnson has made extensive contributions to the literature with over 500 articles, book chapters and abstracts published. Dr. Johnson has given hundreds of invited lectures throughout the world and has been a regular participant in national and international educational meetings with a particular focus and interest and expertise in esophageal and colon disease. Dr. Johnson has served as an editor and reviewer on numerous medical journals, was selected by the American Board of Internal Medicine to serve on the Gastroenterology Subspecialty Examination Committee, has extensive involvement with clinical research including generation of protocols and participation in Phase 1, 2, 3 and 4 studies, has held numerous consultant and advisory positions, and has been extensively involved in leadership positions for both state and national associations and societies.

Dr. Johnson will provide testimony about the biochemical pathways related to gastric acid secretion and control and the etiology and physiologic consequences of gastric acid related diseases and the skill and expertise ordinarily involved with treating such diseases. He will explain that there were numerous therapies being employed and investigated for the treatment of gastric acid related diseases. He will also testify as to the ordinary and customary meaning of certain claims terms with respect to certain skills, experience and practice that a person of ordinary skill in the art would have possessed in treating diseases or disorders of the gastrointestinal tract. Dr. Johnson will testify that the ordinary and customary meanings of certain claim terms encompass Hanmi's proposed products either literally or under the doctrine of equivalents.

Dr. Johnson will testify that the term proton pump inhibitor is reasonably conveyed to a person of ordinary skill in the art in the application that issued as U.S. Patent No. 5,877,192 and in the applications to which it claims priority. Dr. Johnson will also testify that the prior art would not provide a person of ordinary skill in the art with a reason to select an enantiomer of omeprazole or esomeprazole for further study. Dr. Johnson will explain that a person of ordinary skill in the

art would have appreciated a wide spectrum of known and experimental approaches for the treatment of gastric acid related diseases.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. JUDI WEISSINGER

Dr. Weissinger is a consultant at Weissinger Solutions, Inc., where she provides strategic advice on FDA filings concerning pharmaceutical and biological products. Dr. Weissinger is an expert in FDA policy, particularly as it concerns the development of chiral drugs, and will testify in rebuttal to Hanmi's obviousness and obviousness-type double patenting defenses.

Dr. Weissinger obtained a B.S. from the University of Iowa in 1968 and a Ph.D. in medical science (with an emphasis on pharmacology) from the University of New Mexico School of Medicine in 1977. Following a stint in academia, she joined the FDA in 1984, where she held various positions until departing in 1992. Notably, between 1988 and 1992 she was Assistant Director, Office of Drug Evaluation I and II at the Center for Drug Evaluation and Research, the branch of the FDA responsible for new drug evaluation and approval. Among her responsibilities in this role, Dr. Weissinger co-chaired the Stereoisomer Policy Committee, and drafted a policy statement concerning the development of chiral drugs. After leaving the FDA, Dr. Weissinger worked in regulatory affairs and compliance at various pharmaceutical companies before founding Weissinger Solutions, Inc. in 1996.

In rebuttal to Hanmi's obviousness and obviousness-type double patenting defenses, Dr. Weissinger will explain that the FDA did not, and does not, require new drug applicants to prepare and test, or develop, individual enantiomers of chiral drugs. She will testify that the Stereoisomer Policy Committee spent years collecting and evaluating internal and external data to determine whether to institute any such requirement. She will explain that the Stereoisomer Policy Committee concluded that there was no reason to discourage the continued development of chiral drugs in racemic form, and that the FDA policy statement that she drafted does not convey anything different.

SUMMARY OF ANTICIPATED TRIAL TESTIMONY OF DR. PAUL A. BARTLETT

Dr. Bartlett is Professor Emeritus at the University of California, Berkeley. Dr. Bartlett has been actively involved with the drug discovery industry since 1971, and has founded or consulted with over 20 companies involved in drug discovery, including serving as a scientific advisory board member for Celgene, SmithKline Beecham, Sandoz, Amgen and Novartis, among others. As an expert in drug discovery, Dr. Bartlett will testify in rebuttal to Hanmi's obviousness and obviousness-type double patenting invalidity defenses.

Dr. Bartlett obtained an A.B. and A.M. in Chemistry from Harvard University in 1969 and a Ph.D. in Organic Chemistry from Stanford University in 1972. Dr. Bartlett began teaching at Berkeley in 1973 and was Chair of the Department of Chemistry from 1996 to 2000. His teaching responsibilities included medicinal chemistry and drug discovery. He also led a research group in the fields of bioorganic chemistry and synthetic organic chemistry—developing strategies medicinal chemists can use to discover biologically active compounds. Over the course of his career he lectured and published extensively, obtained numerous patents, and received several awards in these areas. Dr. Bartlett assumed Emeritus status (retired) in 2003.

Dr. Bartlett will provide testimony about the general process of drug discovery and the variety of expertise ordinarily involved. He will explain, based in part on the testimony of Dr. Johnson, that by May 1993 there were numerous therapies being employed and investigated for the treatment of gastric acid related diseases. He will also testify about the tremendous structural and mechanistic diversity of compounds being actively investigated at this time. He will explain that this state of the art presented numerous possible starting points a hypothetical person of ordinary skill in the art initiating a drug discovery program would consider, and that omeprazole or its enantiomers would not have been promising starting points for further investigation.

Dr. Bartlett will also testify about the various possible chemical modifications that a person of skill in the art could have considered if the structure of omeprazole (or its enantiomers) was chosen to serve as the starting point for a drug discovery program. Based upon the testimony of Mr. Sverker von Unge from AstraZeneca and Drs. Bernhard Kohl and Jorg Senn-Bilfinger from Byk Gulden, all of whom were well aware of the properties of omeprazole and were actively researching in the area of proton pump inhibitors, Dr. Bartlett will explain that the focus of these individuals on analogs of omeprazole rather than on its individual enantiomers is indicative of the nonobviousness of the claimed inventions.

Dr. Bartlett will also explain that there would have been no basis in the prior art for one of ordinary skill to reasonably expect the beneficial properties that esomeprazole and salts of esomeprazole present over prior art forms of omeprazole and its enantiomers.

D

Plaintiffs' Legal Issues

AstraZeneca's Response to Hanmi's objection to including literal infringement in trial:

Hanmi has been on notice of AstraZeneca's literal infringement case for more than 18 months (*see e.g.* November 11, 2011 Declaration of Dr. Stephen G. Davies on Claim Construction at paras. 35-57; March 19, 2012 Supplemental Declaration of Dr. Stephen G. Davies on Claim Construction at paras. 3-27; February 17, 2013 Report of Stephen G. Davies, D.Phil. on Infringement at paras. 66-75; April 8, 2013 Reply Report of Stephen G. Davies, D.Phil., on Infringement at paras. 15-18, 60-62).

A district court may engage in a "rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." *Conoco, Inc. v. Energy & Envtl. Int'l, L. C.*, 460 F.3d 1349, 1359 (Fed.Cir.2006) ("[A] district court may engage in claim construction during various phases of litigation, not just in a *Markman* order."). Rolling claim construction is especially necessary "where issues involved are complex," for example, "due to the nature of the technology." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002). *See also Utah Med. Prods., Inc. v. Graphic Controls Corp.*, 350 F.3d 1376, 1381–82 (Fed. Cir. 2003) (holding that the district court did not err in amending its claim construction during oral arguments for pretrial motions nearly two years after the original construction); *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1316 (Fed. Cir. 2010); *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996); *Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1377 (Fed. Cir. 2005); *Wright Asphalt Prods. Co., LLC v. Pelican Refining Co., LLC*, 2012 WL 1936416, *12 (S.D. Tex. May 29, 2012); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, Civ. No. 09–290, 2012 WL 1203353, at *5 (W.D. Pa. Apr.10, 2012); *Accentra Inc. v. Staples, Inc.*, 851 F.Supp.2d 1205, 1212 (C.D. Cal. 2011); *Itex, Inc. v. Mount Vernon Mills, Inc.*, Nos. 08 C 1224, 05 C 6110, 2011 WL 2470343, at *2 (N.D. Ill. June 20, 2011); *Wireless Ink Corp. v. Facebook, Inc.*, 787 F.Supp.2d 298, 309-10 (S.D.N.Y. 2011); *Mikkelsen Graphic Eng'g Inc. v. Zund Am., Inc.*, No. 07-C-0391, 2011 WL 1330782, at *5–6 (E.D. Wis. Apr.7, 2011).

Based upon the noninfringement and invalidity defenses relied on by Hanmi, AstraZeneca presently understands that trial will involve the following legal issues:

Infringement of '504 and '192 Patents by Hanmi

1. Whether AstraZeneca can prove by a preponderance of the evidence that Hanmi infringed asserted claims 1-6 and 10 of the '504 patent by filing its New Drug Application No. 202342 with the U.S. Food and Drug Administration seeking approval to commercially sell its proposed esomeprazole strontium products, and will infringe asserted method of treatment claim 6 of the '504 patent and asserted claims 1, 2, 10-12 and 23 of the '192 patent if it commercializes its proposed esomeprazole strontium products, either literally or under the doctrine of equivalents.

2. Whether the term "alkaline" salt of the (–)-enantiomer of omeprazole in claims 1 and 6 of U.S. Patent No. 5,714,504 ("the '504 patent") and the term "pharmaceutically acceptable" salt of the (–)-enantiomer of omeprazole in claim 1 of the '192 patent, both terms having been previously construed by the Court to mean the Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ (where R is

alkyl having 1-4 carbon atoms) salt of the (–)-enantiomer of omeprazole, should instead be construed to mean a basic salt of the (–)-enantiomer of omeprazole that is suitable for use in a pharmaceutical formulation.

3. If the claim terms set forth in legal issue 2 are construed as set forth therein, instead of as previously construed by the Court, whether AstraZeneca can prove by a preponderance of the evidence that Hanmi infringed asserted claims 1, 2 and 4 of the '504 patent by filing its New Drug Application No. 202342 with the U.S. Food and Drug Administration seeking approval to commercially sell its proposed esomeprazole strontium products, and will infringe asserted method of treatment claim 6 of the '504 patent and asserted claims 1, 2, 10-12 and 23 of the '192 patent if it commercializes its proposed esomeprazole strontium products, literally.

4. Whether certain terms in the asserted claims of the '504 patent (*i.e.*, "pure solid state alkaline" salts of the (–)-enantiomer of omeprazole) and '192 patent (*i.e.*, "proton pump inhibitor consisting essentially of" the (–)-enantiomer of omeprazole or "pharmaceutically acceptable" salts thereof) encompass Hanmi's esomeprazole strontium tetrahydrate.

5. Whether the asserted claims of the '192 patent encompass the administration of Hanmi's product to one mammal in need of treatment.

Alleged Invalidity of the '504 Patent-Obviousness-Type Double Patenting

6. Whether Hanmi can prove by clear and convincing evidence that U.S. Patent No. 4,738,974 ("the '974 patent") is eligible to serve as a reference patent for obviousness-type double patenting because it shares a common assignee or inventor with the '504 patent.

7. If the '974 patent is eligible to serve as a reference patent for obviousness-type double patenting, whether Hanmi can prove by clear and convincing evidence that the '974 patent or any prior art to the '504 patent would have been sufficient to enable a PHOSITA to make and use the "alkaline" salts of the (–)-enantiomer of omeprazole in the asserted claims of the '504 patent (including a "pure solid state alkaline" salt of the (–)-enantiomer of omeprazole in at least 98% e.e., or in "substantially crystalline form").

8. If the '974 patent is eligible to serve as a reference patent for obviousness-type double patenting, whether Hanmi can prove by clear and convincing evidence that the subject matter claimed in the asserted claims of the '504 patent (including a pharmaceutical composition containing or a method of administration with a "solid state alkaline" salt of the (–)-enantiomer of omeprazole in at least 98% enantiomeric excess, or "e.e.", or in "substantially crystalline form") is described by the subject matter claimed in claims 5, 9 and 13 of the '974 patent under an anticipation theory of obviousness-type double patenting.

Alleged Invalidity of the '192 Patent-Anticipation

9. Whether Hanmi can prove by clear and convincing evidence that the asserted claims of the '192 patent (issued from a patent application filed April 11, 1997) are anticipated by published patent application WO 94/27988 (published December 8, 1994) under 35 U.S.C. § 102(b) because those asserted claims are not entitled to the May 27, 1994 filing date of an

earlier-filed U.S. patent application under 35 U.S.C. § 120, or the May 28, 1993 filing date of an earlier Swedish patent application under 35 U.S.C. § 119.

Alleged Invalidity of '504 and '192 Patents-Hydrated Forms Not Described or Enabled

10. Whether solvated forms, including hydrated forms, of the claimed "alkaline" salts and "pharmaceutically acceptable" salts of the (–)-enantiomer of omeprazole must be described in the '504 and '192 patent specifications to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph as to the asserted claims.

11. If solvated forms, including hydrated forms, are required to be described under 35 U.S.C. § 112, first paragraph, whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure of the '504 and '192 patent application specifications to contain an adequate written description of solvated forms, including hydrated forms, of the claimed "alkaline" salts of the (–)-enantiomer of omeprazole and "pharmaceutically acceptable" salts of the (–)-enantiomer of omeprazole.

12. Whether solvated forms, including hydrated forms, of the claimed "alkaline" salts and "pharmaceutically acceptable" salts of esomeprazole must be enabled by the '504 and '192 patent specifications to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph as to the asserted claims.

13. If solvated forms, including hydrated forms, are required to be enabled under 35 U.S.C. § 112, first paragraph, whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure of the '504 and '192 patent application specifications and other knowledge available at the time each was filed to enable a PHOSITA to make and use solvated forms, including hydrated forms, of the claimed "alkaline" salts of the (–)-enantiomer of omeprazole and "pharmaceutically acceptable" salts of the (–)-enantiomer of omeprazole without undue experimentation.

Alleged Invalidity of '504 and '192 Patents-Salt Scope Not Described or Enabled

14. Whether Hanmi can prove by clear and convincing evidence that the asserted claims of the '504 and '192 patents are invalid under 35 U.S.C. § 112, first paragraph, for failure of the patent application specifications and other knowledge available at the time each was filed to enable a PHOSITA to make and use either the claimed salts of (–)-omeprazole other than the sodium (Na^+) and magnesium (Mg^{2+}) salts of (–)-omeprazole, or strontium salts of (–)-omeprazole, without undue experimentation.

15. Whether Hanmi can prove by clear and convincing evidence that the asserted claims of the '504 and '192 patents are invalid under 35 U.S.C. § 112, first paragraph, for failure of the '504 and '192 patent application specifications to contain an adequate written description of the claimed salts of (–)-omeprazole other than the sodium (Na^+), magnesium (Mg^{2+}), lithium (Li^+), potassium (K^+), calcium (Ca^{2+}) or ammonium ($N^+(R)_4$ wherein R is an alkyl with 1-4 carbon atoms) salts of (–)-omeprazole.

Invalidity of '504 Patent-Indefiniteness

16. Whether Hanmi can prove by clear and convincing evidence that the asserted claims of the '504 patent are invalid under 35 U.S.C. § 112, second paragraph, because the claim term "pure" is indefinite.

17. Whether Hanmi can prove by clear and convincing evidence that asserted claim 4 of the '504 patent is invalid under 35 U.S.C. § 112, second paragraph, because the claim term "substantially crystalline" form is indefinite.

Invalidity of '504 and '192 Patents-Anticipation based on Kohl

18. Whether Hanmi can prove by clear and convincing evidence that Kohl (DE 40 35 455) or any prior art to the '504 and '192 patents would have been sufficient to enable a PHOSITA to make and use the "alkaline" salts of the (–)-enantiomer of omeprazole or the "pharmaceutically acceptable salt" of the (–)-enantiomer of omeprazole in the asserted claims of the '504 and '192 patents (including a "pure solid state alkaline" salt of the (–)-enantiomer of omeprazole in at least 98% e.e., or in "substantially crystalline form").

19. Whether Hanmi can prove by clear and convincing evidence that the subject matter claimed in the asserted claims of the '504 and '192 patents (including a pharmaceutical composition containing or a method of administration with a "solid state alkaline" salt of the (–)-enantiomer of omeprazole in at least 98% enantiomeric excess, or "e.e.", or in "substantially crystalline form" and "pharmaceutically acceptable salt" of the (–)-enantiomer of omeprazole) is described by Kohl.

Invalidity of '504 and '192 Patents-Obviousness based on Kohl

20. Whether Hanmi can prove by clear and convincing evidence that the differences between the claimed invention and Kohl are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

E

A. Hanmi's Responses To AstraZeneca's Statement of Infringement Issues

1. Objection To Reargument of Markman Rulings and Literal Infringement

Following AstraZeneca's announcement on Sunday May 12th that it intends to seek to re-litigate certain claim constructions and assert literal infringement, the parties presented their views to Judge Pisano on the record Monday. Subsequently, Ms. Bray advised counsel by email that Hanmi could present its objection in the Pretrial Order, along with an explanation of the issues that would be raised by permitting re-litigation. Hanmi provides its views as requested.

Given the Court's *Markman* rulings on "alkaline salt" ('504 claims) and "pharmaceutically acceptable salt" ('192 claims) – "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt" – no issue of literal infringement is framed for trial based on Hanmi's Proposed Products containing an esomeprazole strontium salt as the active ingredient.

Hanmi objects to AstraZeneca attempting to assert that the Court should reconsider its claim construction regarding the "salt scope" of the asserted claims. At the May 13, 2013 hearing on motions *in limine*, counsel for AstraZeneca expressed a desire for the Court to "reconsider" its construction, but such a position has already been rejected in the Court's December 12, 2012 Order (D.I. 257), and again on denial of a motion for reconsideration (D.I. 282). Hanmi has tailored its trial presentation to the Court's once-affirmed *Markman* ruling. To permit AstraZeneca to have a *third* bite at the apple in attempting to convince the Court of error in its well-reasoned prior two decisions would frustrate the principles of judicial economy, and severely prejudice Hanmi.

The *Markman* hearing was conducted in this case to construe the meaning of disputed claim terms so that they would be settled for trial purposes. *Novartis Corp. v. Teva Pharmaceuticals USA, Inc.*, 565 F. Supp. 2d 595, 603 (D.N.J. 2008) ("The purpose of a *Markman* hearing is for the court and the parties to settle conclusively on the interpretation of disputed claims."); *Metrologic Instruments, Inc. v. Symbol Technologies, Inc.*, 460 F. Supp. 2d 571, 582 (D.N.J. 2006) ("The purpose of a *Markman* hearing is for the court and the parties to settle conclusively on the interpretation of disputed claims."); *MacNeill Eng'g Co., Inc. v. Trisport, Ltd.*, 126 F. Supp. 2d 51, 54 (D. Mass. 2001) *dismissed*, 15 Fed. App'x 835 (Fed. Cir. 2001) ("the best time to hold the *Markman* hearing is at the summary judgment stage of the litigation-at or near the close of discovery while some time yet remains before trial for the parties to gear up (or settle) in light of the judge's claim construction."). Hanmi reasonably believed the claim constructions were conclusively set for trial after this Court's claim construction Order, and certainly after the Court denied AstraZeneca's first motion for reconsideration.

Indeed, Hanmi has prepared for trial based on the claims as construed, because the central issues in this case are based on those constructions. *Loral Fairchild Corporation v. Victor Company of Japan, Ltd.*, 911 F.Supp. 76, 79 (E.D.N.Y.1996) (Rader, J. sitting by designation) (plaintiff not allowed to present new theory of liability after *Markman*, and finding that "[t]he meaning of claim terms is the central issue of patent litigation. With most

aspects of trial hinging on this determination . . . a conscientious court will generally endeavor to make this ruling before trial."). With just days to go before trial, AstraZeneca now seeks to present a literal infringement case – which it can only do based on a construction of certain claim terms that AstraZeneca sought but which were not granted.

If the Court permits AstraZeneca's literal infringement case to proceed (based on a construction of claim terms it sought but did not get), fairness would require that Hanmi be permitted to introduce evidence pertaining to invalidity and non-infringement based upon all of the claim constructions it sought but which were not ordered – for example, Hanmi should be entitled to try the case in the alternative, without the optical purity (e.e.) values in the claims, for which Hanmi sought broader constructions during the *Markman* phase.

Courts have not allowed unsuccessful parties to try cases based on claim constructions previously rejected by the court. *LP Matthews LLC v. Bath & Body Works, Inc.*, 458 F. Supp. 2d 198, 210 (D. Del. 2006) ("to the extent that the court's claim construction and related decisions are inconsistent with the opinions expressed in … [the parties'] respective expert reports, such opinions will not be admitted at trial."); *Eaton Corp. v. Parker-Hannifin Corp.*, C.A. No. 00-751-SLR, 2003 U.S. Dist. LEXIS 1014, at * 4 (D. Del. Jan. 24, 2003) (excluding defendant from using testimony that is inconsistent with the court's claim construction.); *Rambus, Inc. v. Infineon Technologies AG*, 145 F. Supp. 2d 721, 735 (E.D. Va. 2001) (plaintiff not permitted to introduce new infringement theories after claim construction, where such testimony would be "highly prejudicial to the ability of …[Defendant] to mount a defense which it has prepared based on entirely different theories."); *Daiichi Pharm. Co., Ltd. v. Apotex, Inc.*, CIV.03-937(WGB), 2006 WL 2065049, at *1 (D.N.J. July 21, 2006) (striking defendant's claim interpretations submitted after *Markman* claim construction). Rather than narrowing triable issues by agreeing to no literal infringement based on both the Court's claim construction and the subsequent denial of AstraZeneca's motion for reconsideration, AstraZeneca seeks to *expand* the scope of the imminent trial in complete disregard of the Court's prior Orders on claim construction.

AstraZeneca's disagreement with the Court's claim construction is properly left to the appeal process; it should not be permitted to argue a third time matters twice decided by this court. *Prall v. Bocchini*, CIV.A. 10-1228 JBS, 2012 WL 5465161, at *2 (D.N.J. Nov. 7, 2012) (denying plaintiff's second motion for reconsideration and finding that "[plaintiff's] only recourse, if he disagrees with this Court's decision, should be via the normal appellate process. He may not use this second motion for reconsideration to re-litigate a matter that has been thoroughly adjudicated by the Court.").

Changing the scope of the case to permit introduction of claim construction and literal infringement would unduly complicate the scope of the trial at the eleventh hour, and result in severe prejudice to Hanmi. Under the above authority, Hanmi had every right to prepare for trial based on the Court's claim constructions, and especially after the denial of AstraZeneca's motion for reconsideration. Changing the scope of the case at this juncture would create the following issues:

1. Hanmi's pretrial preparations have not included re-litigation of claim construction on salt scope, the need for Hanmi to take alternative invalidity positions not fully expressed in its expert reports, or the need to try the case on contingent levels -- one based on the current claim constructions, and one based on alternate, broader constructions. The parties have worked diligently to narrow the issues for trial. In this regard, Hanmi has omitted certain otherwise meritorious defenses simply based on sheer volume of the evidence. To now broaden the scope based on AstraZeneca's last minute notice that it intends to ask the Court to revisit claim scope a third time is fundamentally at odds with Hanmi's good faith narrowing of the issues for trial over the last several weeks.

2. Hanmi's invalidity defenses will change based on a broader claim scope. Under the broadened scope, the asserted claims are invalid based on 35 U.S.C. § 112, first paragraph, for lack of written description because a broad genus of salts is not described, nor was it possessed by the inventors. Hanmi's existing defenses under 35 U.S.C. § 112, first paragraph, for lack of written description and enablement based on hydrates, and also for lack of enablement based on salt scope, also change because a broader genus of salts is present for challenge. Hanmi's case as set out in its expert reports is not presently postured for such expanded invalidity defenses. Having to go forward on these issues at trial would severely prejudice Hanmi.

3. In the course of narrowing issues for trial and assessing strategy, Hanmi's defense that the asserted claims are invalid under 35 U.S.C. § 102 and/or 103 based on the Kohl reference (DE 40 35 455 ("Kohl" or "DE '455)) was removed from Hanmi's list of invalidity defenses. However, under a broadened claim scope, Kohl is of more significance and would need to be reasserted. And, if AstraZeneca is permitted to try the case on its alternate broader salt scope theory, Hanmi should have the equal right to try its case on an alternate broader theory, based on the claims omitting specific optical purity values determined in the claim construction order (D.I. 257). In any case, with the possibility of claim construction changes and alternative trial theories, Hanmi needs to present this prior art defense.

4. If the Court were to permit literal infringement to be added now, presumably there would be expert testimony from both sides on the issue of salt scope claim construction, including cross-examinations, along the lines of the substantial *Markman* record. In fairness, if AstraZeneca is permitted to try an alternative case, Hanmi should be permitted to try an alternative claim construction case as well.

In sum, Hanmi asks that trial proceed on the claim constructions of record as a matter of fundamental fairness and due process, without having to incur the above prejudicial effects.

2. Hanmi's Other Positions On Infringement Issues

a. Hanmi contends that AstraZeneca cannot prove that Hanmi will infringe the asserted claims of the '504 and '192 patents under the doctrine of equivalents, based on the different salts, because there are substantial differences. Hanmi agrees that AstraZeneca's legal issues 1 and 5 are accurate, if limited to an assertion of infringement under the doctrine of equivalents.

b. Hanmi does not agree that AstraZeneca's legal issues 2 and 3 raise proper issues for trial, for the reasons set forth above.

c. In response to AstraZeneca's legal issue 4, Hanmi contends that upon commercialization, neither its products nor their use will infringe any asserted claims of the '504 and '192 patents, because AstraZeneca cannot prove that the asserted claims encompass hydrated forms of the claimed salts as active ingredient, and Hanmi's Proposed Products contain esomeprazole strontium tetrahydrate as the active ingredient. This is an independent distinction from the differences in salts.

B. Hanmi's Invalidity Defenses

1. If the asserted claims of the '504 and '192 patents are determined to encompass hydrated forms of the active ingredient (the salts of (-) omeprazole as construed by the Court), the asserted claims are invalid under 35 U.S.C. § 112, first paragraph, based on lack of written description and/or lack of enablement of hydrated forms of the active ingredient. These defenses are in the alternative to Hanmi's non-infringement position stated above, i.e., that the asserted claims do not encompass such hydrated forms. These defenses present the following specific issues:

1a. If the asserted claims of the '504 and '192 patents are determined to encompass hydrated forms of the active ingredient, whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

1b. If the asserted claims of the '504 and '192 patents are determined to encompass hydrated forms of the active ingredient, whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

2. The asserted claims of the '504 and '192 patents are invalid under 35 U.S.C. § 112, first paragraph, based on lack of enablement, as related to salt scope of the active ingredient (the salts of (-)-omeprazole as construed by the Court). These defenses present the following specific issues:

2a. Whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, based on the salt scope of the claims as construed by the Court and as purported to encompass strontium salts of (-)-omeprazole.

2b. In the event the Court permits re-litigation of claim construction at trial, and the construction changes purporting to literally encompass strontium and other salts of (-)-omeprazole beyond those included within the Court's current constructions, whether Hanmi can prove by clear and convincing evidence that those claims are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

3. The asserted claims of the '504 patent are invalid for non-statutory double patenting based on AstraZeneca's prior U.S. Patent 4,738,974. This defense presents the following specific issues:

3a. Whether Hanmi can prove by clear and convincing evidence that the asserted claims are invalid for double patenting, based on the disclosure of claims 5, 9 and 13 of the '974 patent.[1]

4. The asserted claims of the '192 patent are invalid as being anticipated by WO 94/27988 (WO' 988), which qualifies as prior art under 35 U.S.C. §§ 102(a), 102(b) and/or on non-statutory grounds by admission. Under stipulation for trial no. 6, this defense raises the following issues:

4a. Whether AstraZeneca can prove that either or both of representative claims 1 and 23 of the '192 patent are entitled to the benefit of the filing date of an earlier application that is prior to the date of publication of WO '988, by showing that the full scope of claim 1 and/or claim 23 is described in any such prior application in the manner required by 35 U.S.C. § 112, first paragraph.

4b. Regardless of whether AstraZeneca can meet its burden under paragraph 4a, whether Hanmi can establish that WO '988 qualifies as prior art based on admissions ("admitted prior art").

5. The asserted claims of the '504 patent are invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness based on the claim language "pure" as modifying the active ingredient. Hanmi agrees with AstraZeneca's statement of legal issue 16.

6. Claim 4 of the '504 patent is invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness based on the claim term "substantially crystalline." Hanmi agrees with AstraZeneca's statement of legal issue 17.

7. In the event the Court permits re-litigation of claim construction at trial, and the construction changes purporting to encompass other salts of (-)-omeprazole beyond those included within the Court's current constructions, the asserted claims of the '504 and '192 patents are invalid under 35 U.S.C. § 102(b) and § 103 over the Kohl DE '455 prior art reference. These defenses present the following specific issues:

7a. Whether Hanmi can prove by clear and convincing evidence that any one or more of the asserted claims is anticipated by Kohl DE '455, which qualifies as a prior art reference under 35 U.S.C. § 102(b).

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[1] Hanmi disagrees with AstraZeneca's characterizations of Hanmi's invalidity defenses as set forth in Exhibit D, regarding, *e.g.*, double patenting, anticipation based on Kohl, Section 112 defenses, etc.

7b. As to any asserted claim of the '504 or '192 patents found not to be anticipated by Kohl DE '455, whether Hanmi can prove by clear and convincing evidence that the subject matter of any such claims would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, a) in view of Kohl DE '455 alone, or b) in view of Kohl DE '455 taken together with one or more secondary references, including EP 0 166 287 (if found not to be incorporated by reference into Kohl) and Jacques et al., Enantiomers, Racemates and Resolutions (Krieger Publishing Co., 1991).

8. In the event the Court permits re-litigation of claim construction relating to "alkaline salt" and "pharmaceutically acceptable salt" at trial, Hanmi will seek to assert that the following claims constructions from D.I. 257 should be re-litigated at trial: a) asserted claims 1, 3-6 and 10 of the '504 patent are limited to the salts of (-)-omeprazole having a minimum of optical purity of 94% e.e.; b) asserted claim 2 of the '504 patent are limited to the salts of (-)-omeprazole having a minimum of optical purity of 98% e.e.; and c) asserted claims 1, 2, and 10-12 of the '192 patent are limited to (-)-omeprazole or the salts thereof having a minimum of optical purity of 98% e.e. Under these circumstances, Hanmi seeks to assert the claim constructions as set forth in its opening *Markman* brief (D.I. 132), and the Joint Claim Construction Statement (D.I. 92).